



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Mr. Mark T. Zajac, P. Eng.
Quality Engineer and Regulatory Affairs
Excel Tech Ltd.
2892 Portland Drive
Oakville, Ontario
Canada L6H 5W8

Re: K991900
Trade Name: XLTEK PSG-40 Polysomnography Headbox
Regulatory Class: II
Product Code: GWQ
Dated: June 3, 1999
Received: June 4, 1999

Dear Mr. Zajac:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

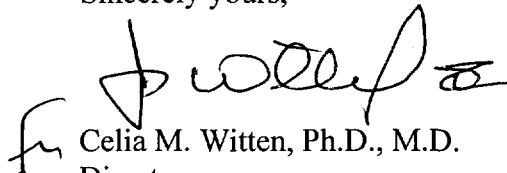
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 – Mr. Mark T. Zajac, P. Eng.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read 'C. Witten', with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

EXCEL TECH, LTD.

510(k) NOTIFICATION OF A NEW DEVICE : "XLTEK PSG-40 POLYSOMNOGRAPHY HEADBOX"

ATTACHMENT # 1

STATEMENT OF INDICATIONS FOR USE

Page 1 of 1

510(k) Number (if known) : K991900

Device Name : XLTEK PSG-40 Polysomnography Head box

Indications for Use :

The XLTEK PSG-40 may be used for sleep recordings (polysomnography) in research or clinical environments for:

- Digital recording of high-level output signals (such as EEG, respiratory and oximetry signals) from conventional polygraphic recorders, signal transducers or amplifiers
- Selection of recorded signal sections for on-screen review, annotation and marking of sleep stages
- Computer-assisted event marking and quantitative analysis of EEG, respiratory and oximetry signals
- Computer-assisted reporting of simple measures obtained from the recorded signals (such as magnitude, time and frequency and simple statistical measures of marked events)

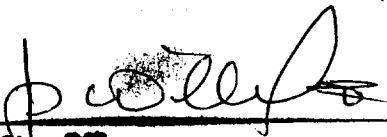
The PSG-40 is not intended to replace conventional devices or methods used for sleep monitoring in critical care or intra-operative settings.

The PSG-40 requires competent user input, and its output must be reviewed and interpreted by trained polysomnographers or neurologists who will exercise professional judgement in using this information.

The PSG-40 does not make any judgement of normality or abnormality of the displayed signals or the results of an analysis. In no way are any of the functions represented as being in and of themselves diagnostic.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Official Sign-Off)
Division of **General Restorative Devices**
510(k) Number K991900

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The Counter Use _____

(Optional Format 1-2-96)